Van Zundert J, Patijn J, et al. Pulsed radiofrequency adjacent to the cervical dorsal root ganglion in chronic cervical radicular pain: A double blind sham controlled randomized clinical trial. Pain 2007;127:173-182.

Design: Randomized clinical trial

Population/sample size/setting:

- 23 patients (10 men, 13 women, mean age 47) treated for chronic cervical radicular pain in a University anesthesiology department in the Netherlands
- Eligibility criteria were 6 months or more of neck pain radiating over the posterior shoulder area in a pattern suggesting involvement of a cervical nerve root, not relieved by physical therapy and TENS, with intensity at least 35 on a scale from 0-100, and with a positive Spurling test
- Exclusion criteria were age under 20 or over 75, with a history of cancer, cervical vertebral fractures, myelopathy, fusion , or laminectomy; also shoulder pathology, several systemic diseases, presence of cardiac pacemaker, spinal cord stimulator, or previous radiofrequency treatment of the cervical dorsal root ganglion (DRG)
- Patients with a score of 45 or higher on the Pain Catastrophizing Scale were not excluded for that reason, but were referred to the psychologist for further evaluation

Main outcome measures

- Cervical level of involvement was confirmed by diagnostic blocks using fluoroscopic imaging
- All patients went to the operating room, where a computer-generated randomization envelope was opened as soon as the intervention cannula was placed in the cervical region
- All patients had placement of the RF probe and stimulation at a frequency of 50 Hz, sufficient to elicit a paresthesia indicating proximity to the DRG
- Randomization was to pulsed radiofrequency (n=11) for 120 seconds or sham intervention (n=12) with the same starting and ending time for all procedures; the display of the pulse generator was turned away from the patient and auditory signals were turned off
- The randomization did not perfectly balance the known prognostic variables; the sham group was 10 years older and had mean VAS scores 21 points higher than the RF group
- Success, defined as 50% reduction in pain 3 months after the procedure, was recorded in 9 of 11 RF and 4 of 12 sham patients
- A 20 point reduction in VAS was recorded in 9/11 RF and 3/12 sham patients at 3 months
- The odds ratios for success at 3 months were not changed when adjusted for baseline differences (variables in the adjustment not specified); the adjusted odds ratio at 6 months did not reach statistical significance

- Pain medication use at 3 months was higher than baseline in only 1 RF but in 5 sham patients; use was equal to baseline in 4 RF and 3 sham patients; it was lower in 6 RF and 4 sham patients

Authors' conclusions:

- Pulsed RF of the cervical DRG may provide pain relief for a limited number of carefully selected patients with radicular pain arising from the spinal nerve roots due to disc herniation or due to narrowing of the intervertebral foramen
- The limited number of patients limits the power of the study, but participation rates are low when patients are reluctant to enter a sham controlled trial and referring specialists may influence the patient not to participate

Comments:

- Methodologically, there is good control of bias: the randomization envelope was opened in the operating room with the cannula in place, ensuring concealment of allocation; all patients had induction of paresthesia with the probe, and the display of the pulse generator was concealed from the patient
- The numbers are small, making any estimate of the effect of RF very uncertain
- The unadjusted and adjusted odds ratios in Figure 5 are very close in value, suggesting that the baseline variables which were adjusted for did not confound the treatment effect
- However, the authors did not report which baseline variables were adjusted for; when there are very few events in a very small sample, only one variable can be reasonably adjusted for
- The adjusted estimates (dark bars in Fig. 5) are slightly wider than the crude estimates; this is not surprising, since adjustment for variables which are correlated with the treatment will widen the confidence intervals without biasing the odds ratio
- Because the primary outcomes were reported as changes from baseline, the higher baseline score in the sham group would, on the basis of regression to the mean, be expected to slant the change scores in favor of the sham group
- Therefore, the baseline imbalance is not likely to bias the results

Assessment: Adequate for evidence that pulsed RF may alleviate pain in patients in which there is a high degree of certainty that the pain arises from a single nerve root, but that results past 3 months are not certain